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September 19, 2011



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United States Environmental Protection Agency - East
Attn: TSCA Section 8(e)
Room 6428
1201 Constitution Avenue, NW
Washington, DC 20004

Subject: Notice in Accordance with Section 8(e): Results of a Reproduction/Developmental Toxicity Screening Test with Orasol Black RLI (CAS No. 117527-94-3)

Dear Section 8(e) Coordinator:

BASF Corporation is submitting results of a Reproduction/Developmental Toxicity Screening Test with Orasol Black RLI (CAS No. 117527-94-3), conducted by BASF SE, Ludwigshafen, Germany.

The study has been performed according to OECD 421 with the dose levels of 0, 50, 200 and 1000 mg/kg body weight/day via gavage in rats. The high dose was discontinued due to high maternal toxicity.

The following unexpected findings were seen:

Preliminary individual pregnancy and litter data at 50 and 200 mg/kg body weight/day showed reduced live birth and viability indices compared to the control group.

The live birth index was 91.7 – 100.0% in controls (N = 10 dams) and 92.3 – 100.0% at 50 mg/kg body weight/day (N = 9 dams) but 1 rat 50 mg/kg body weight/day had a live birth index of 10.0%. The live birth index at 200 mg/kg body weight/day was reduced to 66.7 – 71.4% (N = 3) and 0.0% (N = 1), only 5 rats were unaffected (100.0%) and one animal did not litter.

The viability index of control animals was 100.0% in all animals. The viability index was reduced at 50 and 200 mg/kg body weight/day due to 2 and 4 rats, respectively, with no pups alive on Day 4.

In addition, pup weights and pup weight gain were low at 200 mg/kg body weight/day. Compared to the control group the pup weight gain was reduced by -15% in males and -30% in females.

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Dose (mg/kg bw/day)	Animal number	Live birth index	Viability index %	Mean pup body weight (day 1)	Mean pup body weight (day 4)	Mean pup body weight gain
Control	41	100.0	100.0	Males 6.9 ± 0.5	Males 10.2 ± 0.8	Males 3.3 ± 0.4
	42	100.0	100.0			
	43	100.0	100.0			
	44	100.0	100.0			
	45	92.9	100.0			
	46	100.0	100.0	Females 6.6 ± 0.5	Females 9.9 ± 0.8	Females 3.3 ± 0.4
	47	100.0	100.0			
	48	100.0	100.0			
	49	91.7	100.0			
	50	100.0	100.0			
50	51	100.0	100.0	Males 6.9 ± 1.0	Males 10.6 ± 1.4	Males 3.4 ± 0.8
	52	100.0	100.0			
	53	100.0	0.0			
	54	100.0	100.0			
	55	100.0	100.0			
	56	100.0	100.0	Females 6.9 ± 0.6	Females 10.3 ± 1.3	Females 3.4 ± 0.8
	57	100.0	100.0			
	58	10.0	0.0			
	59	92.3	100.0			
	60	100.0	100.0			
200	61	0.0	-	Males 6.4 ± 0.6	Males 9.5 ± 0.7	Males 2.8 ± 0.2
	62	100.0	100.0			
	63	100.0	75.0			
	64	100.0	88.9			
	65	66.7	0.0			
	66	66.7	0.0	Females 6.1 ± 0.6	Females 8.2 ± 1.2	Females 2.3 ± 0.6
	67	100.0	77.8			
	68 NL					
	69	71.4	0.0			
	70	100.0	100.0			

NL = not littered



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BASF Corporation understands that reporting of the results from this study under TSCA 8(e) is in accordance with EPA's policy.

If you have any questions, please contact the undersigned at (973) 245-6693.

Sincerely,

Janet Cerra

Janet Cerra
Product Regulatory Center of Expertise
North America

/

1224th Letter.doc

From: (973) 245-6693
 Janet Cerra
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Origin ID: LKKA



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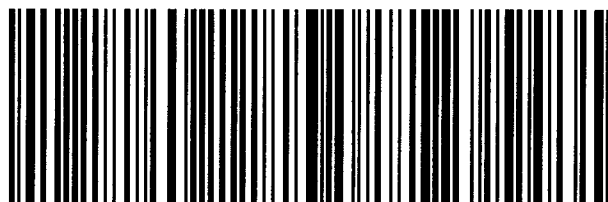
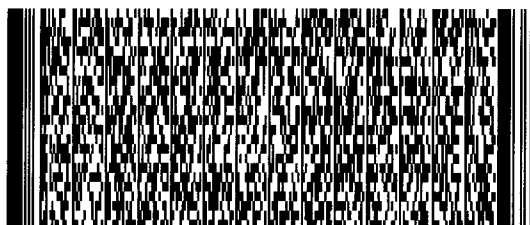
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